Copan

EIFU060R00 Date 2025.01

UriSponge™

Instructions for Use

IVD

English

Copan UriSponge™ - Urine Collection, Transport, and Preservation System Product Insert & How to Use Guide

INTENDED USE

Copan UriSponge™ - Urine Collection, Transport, and Preservation System is intended for the collection, transport and preservation of urine specimens from the collection site to the testing laboratory. In the laboratory, UriSponge™ specimens are processed using standard clinical laboratory operating procedures for the cultivation of uropathogenic bacteria and yeasts.

SUMMARY AND PRINCIPLES

Bacterial and fungal quantification of clean-voided midstream collected urine is widely used to evaluate urinary tract infections (1). The maintenance of the microbial load in urine samples depends on many factors including the type and concentration of the microorganisms, duration of transport and storage temperature (2). The UriSponge™ device contains preservative substances (urine maintenance formula) incorporated onto the applicator sponge within a conical bottom, screw-cap tube, which sustains the viability of clinically important organisms during transport for up to 48 hours at 2–25 °C.

PRESERVATIVE

Copan UriSponge™ has the following preservative substances (urine maintenance formula) incorporated onto the applicator sponge:
Sodium Propionate
Potassium Sorbate

WARNING AND PRECAUTIONS

1. Please read the instructions carefully before use.
2. For In Vitro Diagnostic Use only.
3. This product is for prescription use only.
4. This product is for single use only; reuse may cause a risk of inaccurate results.
5. Copan UriSponge™ is ready for use and requires no further preparation.
6. For professional use only. Use UriSponge™ in accordance with the Package Insert.
7. Do not use if the package or tube is open, there is evidence of damage, deterioration, contamination, or the expiration date has passed.
8. Do not re-sterilize. Do not re-pack.
9. Not suitable for the recovery of fastidious microorganisms, e.g. anaerobes, viruses, chlamydiae, mycoplasmas, ureaplasmas trichomonas, in culture.
10. Not suitable for collection of specimens for microscopic and macroscopic examination.
11. Use of this device in association with diagnostic kits and/or instrumentation should be validated prior to use.
12. Wear protective gloves and other protection commensurate with universal precautions when handling clinical specimens. Observe appropriate CDC Biosafety recommendations. After use, tubes must be disposed of according to laboratory regulations for infectious waste (7,8,9).

DEVICE STORAGE AND SHELF LIFE

Store in the original packaging at 2–25 °C until used. Do not freeze prior to use. Copan UriSponge™ device when stored as directed, is good for up to 12 months from the date of manufacture. Please do not use after the expiration date which is printed on tube or package label.

DEVICE DESCRIPTION / HOW SUPPLIED

Copan UriSponge™ - Collection, Transport and Preservation system is ready-to-use. Product descriptions and packaging configuration are listed in **Table 1**

Figure 1: UriSponge™ device

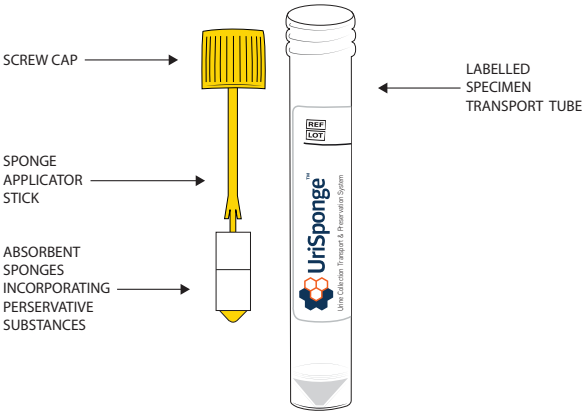


Figure 2: UriSponge™ components

Table 1. UriSponge™ Description and Packaging Configuration

Ref. Number	Copan UriSponge™- Product Descriptions	Pack Size
8U033S50	Plastic sealed bag containing 50 pieces of single use devices composed of mini size sterile plastic tube with screw cap (80 mm length x 12 mm diameter). Inside the tube the cap holds a sponge applicator with two cylinders of hydrophilic polyurethane foam incorporating preservative substances.	50 devices per shelf pack 50 x 6 devices per box

MATERIALS REQUIRED BUT NOT SUPPLIED

Sterile urine collection cup and appropriate materials for the isolation and culture of uropathogenic bacteria and yeast, e.g. culture media and incubation systems are not provided. Refer to laboratory reference manuals for recommended procedures for the culture and identification of uropathogenic bacteria and yeasts from clinical samples (1,4).

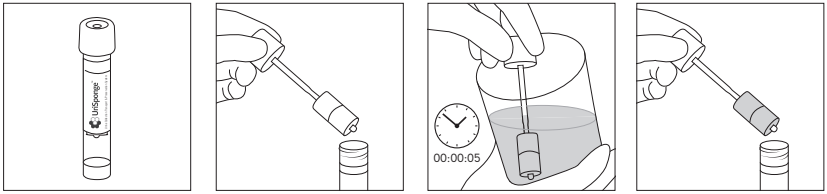
INSTRUCTIONS FOR USE

Specimen Collection and Transport with UriSponge™

Proper specimen collection from the patient is critical for successful isolation and identification of infectious organisms. Specimens obtained for assessment of urinary tract pathogens should be collected and handled following published manuals and guidelines (1, 2, 3,4).

1. Obtain a clean-voided midstream urine sample from the midstream portion into a sterile urine collection container (not provided).
2. Open the UriSponge™ tube and, holding by the cap, dip the sponge applicator into the urine sample. Submerge the sponges for 5 seconds. The polyurethane sponges are extremely hydrophilic and spontaneously absorb urine.
3. Remove the sponge applicator from the urine sample and return it to the UriSponge™ tube. See **Figure 3**. Do not add urine to the tube other than the urine spontaneously absorbed by the sponge.Screw the cap to securely close the container.
4. Label and transport UriSponge™ specimens in accordance with institutional, local, state, and federal requirements (6).
5. Immediately transfer UriSponge™ specimen(s) to the laboratory, preferably within 2 hours of collection (2). If immediate delivery or processing is delayed UriSponge™ specimens may be refrigerated at 2-8 ºC or stored at room temperature (19-25 °C) and processed within 48 hours.

Figure 3: Transfer of urine sample to UriSponge™ device.



Testing UriSponge™ Specimens for Culture in the Laboratory

UriSponge™ specimens should be processed immediately upon receipt and within 48 hours of collection.

1. UriSponge™ tubes may be centrifuged to extract the urine from the sponge. Centrifuge at 104 g for 3 seconds in a swing-out rotor centrifuge. UriSponge™ may be re-centrifuged as needed. Alternatively, the specimen can be manually extracted from the sponge by shaking the device down three times using quick, sharp, downward wrist motions.
2. Using aseptic technique, unscrew the cap and remove the sponge applicator. Gently mix the content of the tube.
3. Follow laboratory internal Standard Operating Procedures (SOPs) for inoculating the urine sample from the tube onto culture media or refer to published microbiology manuals and guidelines (1,4).

LIMITATIONS

1. Condition, timing and volume of specimen collected for culture are significant variables in obtaining reliable culture results. Incomplete immersion or immersion of the sponge applicator for less than 5 seconds may not fully saturate the sponge with urine which may impact downstream microbial recovery.
2. The microbial load in urine from a given patient may be influenced by the time of collection and fluid intake. Symptomatic patients may have counts below 10^5 microorganism/mL if specimens are collected late in the day or if diuresis is occurring (10).
3. The recovery performance was evaluated using the bacteria and yeasts listed in the recovery study, described in the Performance Characteristics section of this Package Insert. The recovery performance of UriSponge™ with bacteria and yeasts beyond the ones listed in the recovery study has not been evaluated.
4. The sponge preservatives will not inactivate antibiotics.

QUALITY CONTROL

UriSponge™ is verified to maintain viability after storage at 2-8 °C (refrigerated) and 19–25 °C (room temperature) for up to 48 hours using the organisms recommended by the Clinical and Laboratory Standards Institute (CLSI) M40-A2 (5).

PERFORMANCE CHARACTERISTICS

Tests were conducted using representative organisms for urine specimen in a pool of negative clinical urine. Urisponge™ was saturated according to the instructions for use. After specimen collection, Urisponge™ device were stored at 2-8°C (refrigeration) and at 19-25°C (room temperature) for 0 hrs. (less than 20-minutes), 24 hrs., and 48 hrs. at 2-8 °C and 19-25°C.

At the end of each incubation period, the devices were centrifuged, and aliquots of released sample were spread onto appropriate agar plates and incubated in appropriate environment for 24-48 hours. Following incubation, colony forming units (CFU) were counted. A colony count of 25-250 per plate for at least one dilution and the ΔLog_{10} ≤1 and ≥ -1 between the average CFU/plate values at time zero (T = 0 hrs.) and at specific specimen incubation time (e.g., 24 hrs., 48 hrs., etc.) were considered acceptable to support a specimen stability claim for each target organism.

Table 2: Microbial recovery results summary of UriSponge™ device.

Organism	Organism concentration at T = 0 hrs. (CFU/mL)	Incubation Temperature	Logarithmic difference in microbial recovery from the baseline (T= 0 hrs.) (-ve indicates reduction)	
			T = 24 hrs.	T = 48 hrs.
C. albicans (ATCC 24433)	$5x10^2$	2-8°C	-0.02	-0,03
		19-25°C	0.18	0.38
E. coli (ATCC 25922)	$1.5x10^3$	2-8°C	-0.11	-0.2
		19-25°C	-0.11	-0.14
E. faecalis (ATCC 29212)	$7.5x10^2$	2-8°C	-0.19	-0.25
		19-25°C	-0.04	-0.07
P. aeruginosa (ATCC 27853)	$1.5x10^3$	2-8°C	-0.10	-0.16
		19-25°C	-0.20	-0.30
P. mirabilis (ATCC 7002)	$7.5x10^2$	2-8°C	-0.08	-0.05
		19-25°C	-0.10	-0.06
S. saprophyticus (ATCC 15305)	$1.5x10^3$	2-8°C	-0.17	-0.21
		19-25°C	-0.16	0.07
E. cloacae (ATCC 13047)	$1.5x10^3$	2-8°C	-0.23	-0.26
		19-25°C	-0.27	-0.29
K. pneumoniae (ATCC 13883)	$1.5x10^3$	2-8°C	-0.11	-0.06
		19-25°C	-0.21	-0.13
S. agalactiae (ATCC 13813)	$1.5x10^3$	2-8°C	-0.35	-0.45
		19-25°C	-0.39	-0.53

The recovery study results met the study acceptance criteria, therefore support the ability of UriSponge™ device to maintain the recovery of the tested microorganisms in urine samples up to 48 hours when stored at 2-8°C or at 19-25°C.
To verify the no toxicity on microbial recovery in case of sponge undersaturation, a fill volume flex study was conducted with the three strains (*E. coli* ATCC 25922, *P. aeruginosa* ATCC 27853 and *S. agalactiae* ATCC 13813) that exhibited the highest log reduction. The results from the fill volume study indicated that there was no significant risk of toxicity to the intended use organism in the urine sample due to undersaturation of UriSponge™ device.

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INDEX OF SYMBOLS

Symbol	Meaning
	Manufacturer
IVD	In vitro diagnostic device
Rx Only	This only applies to US: “Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.”
	Do not reuse
REF	Catalogue number
STERILE R	Sterilized using irradiation
	Temperature limits
	Use-by date
 eIFU Indicator	Consult the operating instructions supplied with the device or available in electronic format, and which can be identified by the e-IFU indicator on the packaging label
LOT	Batch code (lot)
	Contents sufficient for <n> tests
UDI	Unique device identifier
	Sterile barrier system
	Do not resterilize
	Date of manufacture

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